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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
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09/011,745 06/22/98 COLLINS

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HM22/0212

EXAMINER

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SUITE 720  
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GUZO, D

ART UNIT

PAPER NUMBER

1636

90

DATE MAILED:

02/12/99

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

### OFFICE ACTION SUMMARY

Responsive to communication(s) filed on 2/23/98 and 11/24/98

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire Three (3) month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

Claim(s) 1-3 and 30-57 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

Claim(s) 37, 39-40 and 44-52 is/are allowed.

Claim(s) 1-2, 31-33, 36, 38, 41-43 and 53-57 is/are rejected.

Claim(s) 3, 30, 34, 35 is/are objected to.

Claims \_\_\_\_\_ are subject to restriction or election requirement.

#### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

Notice of Reference Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s) \_\_\_\_\_

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

- SEE OFFICE ACTION ON THE FOLLOWING PAGES -

Art Unit: 1636

1. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2, 31-33 and 36 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants claim recombinant expression vectors (and host cells containing said vectors) which express a gene of interest and rely on translation reinitiation to express a marker gene in a manner which would allow for selection of cells which express the gene of interest at high levels.

Applicants have not adequately described the claimed invention, with the exception of retroviral vectors, because applicants have not disclosed any other expression vectors, have not disclosed any procedures for generating said vectors and have not disclosed any cell lines for packaging or producing said vectors. Applicants have not disclosed any of the relevant identifying characteristics of the claimed vectors, except in purely functional terms, in a manner sufficient to describe the claimed invention in such clear, concise and exact terms that a skilled artisan would recognize applicants were in possession of the claimed invention. Applicants have

Att. 2/11/99

Art Unit: 1636

also not disclosed any correlation between the function and structure of the vectors. Therefore, it must be considered that applicants were not in possession of the claimed invention at the time of filing.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 31, 34-35, 38, 41-43 and 53-57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 31 is vague in the recitation of the phrase "...gene of interest is included as part of a viral packaging construct." since it is unclear if the expression vector of claim 1 is a viral packaging construct or whether the viral packaging construct is separate from the expression vector of claim 1 and said viral packaging construct includes the gene of interest from claim 1.

Claim 34 is vague in that while the preamble of the claim recites a process for producing a cell line in which a gene of interest is expressed, no step(s) in the claim refers back to the preamble, i.e. no step(s) recites the production of a cell in which a gene of interest is expressed.

Claim 38 is vague in the recitation of the phrase "...according to claim 37 being human complement-resistant." as this language is confusing. Redrafting the claim to read as --according to claim 37, wherein said retroviral packaging cell line is human complement-resistant.-- would be remedial.

Art Unit: 1636

Claim 41 is vague in that there is no antecedent basis for the term “the packaging deficient construct comprising the viral env gene and the second selectable marker”.

Claim 42 is vague in that it refers to “the recombinant expression vector” from claim 37; however, claim 37 recites two recombinant expression vectors and it is unclear which expression vector is being referred to.

Claim 43 is vague in that there is no antecedent basis for the terms “the retroviral vector” and “the packaging deficient genome”.

Claims 53 and 54 are vague in the phrases “...packaging cells comprises human HT1080 cells...” and “...packaging cells comprises human TE671 cells and express RD114 envelopes.” since it is unclear how a cell can comprise a cell. Redrafting claim 53, for example, to read on -- wherein the retroviral packaging cell is a human HT1080 cell and expresses RD114 envelopes.--

Claim 54 is vague in that it depends from canceled claim 11.

Claim 55 (and dependent claims) is vague in that while the claim recites a method for producing a retroviral packaging cell line in which a gene of interest is expressed, no step(s) in the claim refers back to the preamble, i.e. no step(s) recites the generation of a retroviral packaging cell in which a gene of interest is expressed.

4. Claims 3, 30 and 34-35 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Art Unit: 1636

Claims 37, 39, 40 and 44-52 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo whose telephone number is (703) 308-1906. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, George Elliott, can be reached on (703) 308-4003. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242 or (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

David Guzo  
February 11, 1999

DAVID GUZO  
PRIMARY EXAMINER  
